DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 15, 2014

ASCLEPION LASER TECHNOLOGIES GmbH
Mrs. Antje Katzer
International Regulatory Affairs Manager
Brüesseler Straße 10
Jena 07747, Germany

Re: K131987
Trade/Device Name: MultiPulse HoPLUS
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 8, 2014
Received: October 9, 2014

Dear Mrs. Katzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.10.15 07:49:43 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131987

Device Name

Multipulse HoPLUS

Indications for Use *(Describe)*

The MultiPulse HoPLUS Laser system and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and use in medical specialties including: Urology, Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery.

Urology
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors
- Ablation of Benign Prostatic Hypertrophy (BHP),
- Transurethral incision of the prostate (TUIP)
- Holmium Laser Resection of the Prostate (HoLRP)
- Holmium Laser Enucleation of the Prostate (HoLEP)
- Holmiurm laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of external genitalia

Lithotripsy and Percutaneous Urinary Lithotripsy
- Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate
- dehydrate stones.
- Endoscopic fragmentation of kidney calculi
- Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

Gastroenterology
Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:
- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm • Angiodysplasia
- Colorectal cancer

- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Arthroscopy
Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) in small and large joints of the body, excluding the spine but including:

- Ligament and tendon Release
- Contouring and sculpting of articular surfaces
- Capsulectomy in the knee
- Chondreoplasty in the knee
- Debridement of inflamed synovial tissue
- Chondromalacia Ablation
- Chondromalacia and tears
- Plica Removal
- Meniscectomy
- Loose body Debridement
- Lateral retineacular release

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including
- Percutaneous Laser Disc Decompression/Discectomy of the L4-5 and L5-SI lumbar discs, including Forminoplasty
- Percutaneous Cervical Disc Decompression/Discectomy
- Percutaneous Thoracic Disc Decompression/Discectomy

Pulmonary
Open and endoscopic pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue)

Gynecology
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

ENT
Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue and cartilage) including:

- Endonasal / sinus Surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinustomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery

Dermatology and Plastic Surgery
Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

- Basal Cell Carcinomas
- Lesions of skin and subcutaneous tissue
- Skin tags
- Plantar warts
- Lesions of skin and subcutaneous tissue
- Port Wine Stains
- Papillomas

General Surgery
Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Skin incision
- Excision of external lesions
- Complete or partial resection of internal organs, tumors and lesions
- Biopsy

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
ASCLEPION LASER TECHNOLOGIES GmbH
MultiPulse HoPlus

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH MultiPulse HoPLUS is submitted in accordance with the requirements of 21 CFR 907.92 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant:	ASCLEPION LASER TECHNOLOGIES GmbH Bruesseler Str. 10 07747 Jena, Germany
Contact Person:	Mrs. Antje Katzer Product Management and International Regulatory Affairs
Phone: Fax: e-mail:	+49 3641 77 00 309 +49 3641 77 00 302 antje.katzer@asclepion.com
Preparation Date:	August 28, 2014
Device Name:	MultiPulse HoPLUS
Common Name:	MultiPulse HoPLUS
Classification Name:	Laser surgical instrument for use in general and plastic surgery 79-GEX 21 CFR 878.4810

Equivalent Devices:			
	Auriga XL	K111475	StarMedTec
	Trimedyne Systems	K002308	Trimedyne
	PowerSuite Holmium	K011703	Lumenis

Device Description: The MultiPulse HoPLUS Laser system and its fiber optic delivery system is a laser Class IV, pulsed, solid state Holmium-YAG, which emits laser radiation with a wavelength of approximately 2100 nm with a pulse with between 150-850 microseconds. The laser power up to 110 Watts is transmitted to the tissue through different optical fibers.

The laser system consists of:
Laser system including control panel (user interface)
Foot switch
A variety of application fibers and accessories

Intended Use: The MultiPulse HoPLUS Laser system and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery and General Surgery.

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Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

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- Biopsy

Comparison to:

The Multipulse HoPLUS surgical laser and delivery devices with Accessories share the same intended use, similar design features, functional features, and therefore, is substantially equivalent to the VersaPulse PowerSuite Holmium (Ho:YAG). The Multipulse HoPlus is also substantially equivalent in terms of indications for use to the Auriga XL (K111475) system Trimedyne Holmium Laser Systems (model 1210, model 1010-VHP and model 1500-A) (K002308) and PowerSuite Holmium (K011703) with similar parameters and the same intended use.

Performance Testing:

The MultiPulse HoPLUS laser system is tested according to following standards:

ISO 14971:2009
DIN EN 60601-1:2006
DIN EN 60601-1-2:2007
DIN EN 60601-1-6:2007
DIN EN 60601-2-22:1996
DIN EN 60825-1:2007
DIN EN 62304:2006

The device also complies with European Medical Device Directive 93/42/EEC + Amendment 2007/47/EC.

Conclusion:	The Multipulse HoPLUS is substancially equivalent to the cited legally marked predicate devices. Furthermore, the non-clinical data demonstrate the safety and effectiveness of the device for the treatment of the intended indications.